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DN

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/878,168 06/18/97 ASHKENAZI

A P1110

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HM12/0709

EXAMINER

KAUFMAN, C

ART UNIT

PAPER NUMBER

1646

15

DATE MAILED:

07/09/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/878,168

Applicant(s)

ASHKENAZI ET AL.

Examiner

Claire M. Kaufman

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 1999.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 15-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4-7 is/are allowed.
- 6) ☒ Claim(s) 1-3, 8-11 and 15-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☐ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12, 5.
- 17) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☒ Other: *Notice to Comply*.

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DETAILED ACTION

The amendments filed Feb. 8 and Apr. 21, 1999 have been entered.

Election/Restrictions

5 Applicant's confirmation of election of Group I is acknowledged.

Response to Arguments

The rejection of claims 1, 4-7, and 16-17 under 35 USC 112, second paragraph for
indefiniteness due to parentheses and the use of the term "about" is withdrawn in view of the
10 amendment to the claims and applicants' arguments, respectively.

The rejections of claims 26-27 are moot in view of the cancellation of the claims.

Applicant's arguments filed 2/8/99 have been fully considered but they are not
persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found
15 in a prior Office action.

Drawings

Applicants intention to correct the number of Fig. 8 once allowable subject matter
is indicated is acknowledged.
20

Information Disclosure Statement

Applications 60/035,496 and 60/054,885 have been considered, but will not be printed if
this application issues as a patent since reference to the applications appears on a PCT instead of
an issued US patent.
25

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Sequences

Examiner thanks Applicant for pointing out that on page 64, the sequence of line 1 is continued on line 6 and that of line 2 is continued on line 8. Therefore, the sequence requirement is complied with for that issue. The CRF and sequence Listing filed 2/8/99 has been entered.

5 This application contains sequence disclosures that are encompassed by the definitions for nucleic and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth in the attached Notice to Comply with Requirements for Patent Applications Containing Nucleic Sequence and/or Amino Acid Sequence Disclosures. In the current
10 application, the amino acid symbol "Xaa" appears in SEQ ID NO:10. An explanation of the Xaa must be present in the <200> to <223> fields of the sequence. As a result, a substitute CRF and paper copy of the Sequence Listing with proper explanation fields are required.

Claim Rejections - 35 USC § 112

15 The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 19 and dependent claims 8-11, 15-18 and 20-21 remain rejected under 35
20 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 remain indefinite because it is unclear what is encompassed by the claims since the specification does not define how "identity" is to be calculated and the art has not recognized one way of calculating identity.

25 Applicants argue that the specification on page 13, lines 9-23 defines identity-- specifying that gaps may be used to achieve the maximum percent sequence identity and listing two programs for such calculation. The argument has been fully considered, but is not persuasive. Two alignment programs may provide a maximized % identity for a particular

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sequence comparison, but the percentages may not be the same because optimum parameters between the programs may be different and gap use may not be identical. These are not hypothetical 'mays', but actually occur using different programs. The results also depend on the lengths of each sequence compared, as well as on the number of potential gaps (misalignments) between the sequences. This rejection could be overcome by specifying one of the alignment programs (or listing the programs in the alternative) used in the specification (p. 13, line 19) and specifying the parameters used to calculate the identity (*e.g.*, default parameters, if appropriate).

Claim 19 remains indefinite because it is unclear what the "control sequences" control. If the control sequences control expression, for example, the claim should say so.

Applicants argue that on page 14, lines 29-31 of the specification, "control sequences" refers to DNA sequences necessary for the expression of an operably linked coding sequence in a particular host. The argument has been fully considered, but is not persuasive. Claim 19 says that the control sequences are operably linked to the vector. Vectors typically have antibiotic resistance sequences, the coding sequence of the inserted polynucleotide, often a marker gene (*e.g.*, lacZ). Vectors may also have other coding sequences. Since what is in the vector is not clear, and it is not clear from the claim what the operably linked coding sequence is, the claim remains indefinite. Phrasing, if appropriate, such as "a vector comprising the nucleic acid of claim 15 operably linked to control sequences..." would be clear. Note that claim 19 requires more than a single control sequence to be present.

Claims 1-3 remain indefinite because it is not clear what range is encompassed by "about" 80 [or 90 or 95] %".

Conclusion

Claims 4-7 are allowed.

Claims 1-3 and 19 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

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Claims 8-11, 15-18 and 20-21 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

5 **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after
10 the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Friday from 8:00AM to 4:30PM.

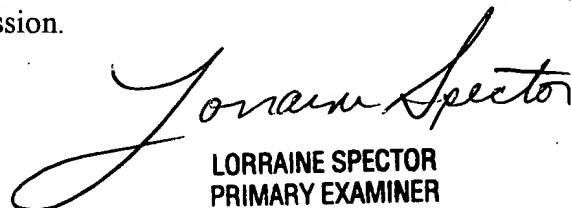
20 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

25 Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office. Please advise the examiner at the telephone number above before facsimile transmission.

30 cmk

July 2, 1999


LORRAINE SPECTOR
PRIMARY EXAMINER

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☐ 7. Other: _____

Applicant Must Provide:

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

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